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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,969	07/28/2003	Stephen M. Allen	BB1107USCNT	8563

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,969	ALLEN ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-39* is/are pending in the application.

4a) Of the above claim(s) *39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-29 and 32-38* is/are rejected.

7)☒ Claim(s) *30 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10 and 21-25 and SEQ ID NO: 31 and 32 in the reply filed on 15 May 2006 is acknowledged. The Examiner acknowledges Applicant's cancellation of the previously pending claims and submission of new claims 27-39.

2. Claim 39 is withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15, May 2006. Claim 39 is not considered commensurate with the elected invention because Group I of the originally restricted claims did not encompass a method of isolating a polypeptide. The Examiner considers claim 39 as non-elected by original presentation. See 37 CFR § 1.142(b) and MPEP § 821.03. Applicant is advised that the invention of claim 39 is not directed to a method of using the product of claim 27, it is directed to a method of using the product of claim 35, and hence as presently presented is not in condition for rejoinder. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

3. New claims 27-38, directed to the elected invention, are under examination in the instant Office action.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 119(e) or under 35 U.S.C. § 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 119 and 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/485,558 or 60/055,865, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of this application. The

amino acid sequence of SEQ ID NO: 32 is not adequately supported in the above application(s), and thus said applications do not provide support under 35 USC § 112, first paragraph for the claimed invention. In addition Provisional Application No. 60/055,865 does not have a common inventor with the instant application. The effective priority date of the instant claimed invention is 20 February 2001, the filing date of parent application 09/789,054.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-29 and 32-38 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having transcriptional repressor activity, wherein the polypeptide and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method. Applicant further claims a chimeric gene and a vector comprising said isolated polynucleotide, a method for transforming a cell comprising introducing said isolated polynucleotide and a plant and seed comprising said chimeric gene.

Applicant describes a rice DRAP1 protein encoded by an isolated polynucleotide having the amino acid sequence shown in SEQ ID NO: 32, for example SEQ ID NO: 31. Applicant only describes a single group of species of nucleic acids that encode SEQ ID NO: 32, which fall within the claimed genus of isolated nucleic acids.

Applicant does not describe other isolated polynucleotide comprising a nucleotide sequence wherein the encoded amino acid sequence and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method, said isolated polynucleotides encode a polypeptide having transcriptional repressor activity.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without

any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, while proteins known to have the transcription regulatory function of DRAP1 have a common secondary structure, the art discloses that other proteins with similar secondary structures can be misclassified as having the required histone fold structure required for DRAP1 activity, for example TFIIB (see Baxevanis *et al* 1998, Nucleic Acids Research 26(1): 372-375, especially page 373, right column, 3rd paragraph). Baxenanis also discloses that proteins having histone fold motifs do not have readily identifiable primary structures either (see figure 1 on page 374).

7. Claims 27-29 and 32-38 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding the amino acid sequence of SEQ ID NO: 32, a chimeric gene and a vector comprising said isolated polynucleotide, a method for transforming a cell comprising introducing said isolated polynucleotide and a plant and seed comprising said chimeric gene, does not reasonably provide enablement for an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having transcriptional repressor activity, wherein the amino acid sequence of said polypeptide and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having transcriptional repressor activity, wherein the polypeptide and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method. Applicant further claims a chimeric gene and a vector comprising said isolated polynucleotide, a method for transforming a cell comprising introducing said isolated polynucleotide and a plant and seed comprising said chimeric gene.

Applicant teaches a rice DRAP1 protein encoded by an isolated polynucleotide having the amino acid sequence shown in SEQ ID NO: 32, for example SEQ ID NO: 31. Applicant only teaches a single group of species of nucleic acids that encode SEQ ID NO: 32, which fall within the claimed genus of isolated nucleic acids.

Applicant does not teaches other isolated polynucleotide comprising a nucleotide sequence wherein the encoded amino acid sequence and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method, said isolated polynucleotides encode a polypeptide having transcriptional repressor activity.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance for how to make and use a polynucleotide encoding a polypeptide having transcriptional repressor activity having at least 85-95% identity to SEQ ID NO: 32 in the instant specification. The nature of the invention is such that the structure of the taught DRAP1 protein of rice is intimately associated functionally with the structure of the DR1 protein of rice to regulate function of RNA polymerase II in a rice cell (see for example Maldonado *et al* 1999, Cell 99: 455-458, especially pages 456-457). Applicant does not teach what changes in the amino acid sequence of SEQ ID NO: 32 one of skill in the art can make and still have a functional protein or fragment thereof as broadly claimed. The art teaches that mutations in the histone fold motifs of the yeast Bur6 protein, which has a similar function to the DRAP1 of rice taught by Applicant, was found to inhibit repressor function (see Kim *et al* 2000, Molecular and Cellular Biology 20(7): 2455-2465, especially page 2455, the top of the right column). Applicant has failed to teach one of skill in the art how to use a polynucleotide encoding a non-functional rice DRAP1 protein. The teachings of Baxevanis *et al* (1998) as outlined above suggests that one of skill in the art cannot predictably change the amino acid sequence of a DRAP1 protein without extensive guidance because there is no unifying feature of the primary structure of a DRAP1 protein that one can recognize the specific function from, and that one of skill in the art cannot infer the specific function even by the secondary structure of the protein, that being a protein having a histone fold structure. Hence, it would have

required one of skill in the art at the time of Applicant's invention undue trial and error experimentation to screen through a myriad of polynucleotides that encode a polypeptide having transcriptional repressor activity having an amino acid sequence at least 85-95% identity to the amino acid sequence of SEQ ID NO: 32 to identify those that could be useful in a method of transforming a cell or a plant cell as broadly claimed.

Allowable Subject Matter

8. Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The claims are free of the prior art which neither teaches nor fairly suggests an isolated polynucleotide comprising a nucleotide sequence wherein the encoded amino acid sequence and the amino acid sequence of SEQ ID NO: 32 have at least 85-95% identity based on the Clustal alignment method, said isolated polynucleotides encode a polypeptide having transcriptional repressor activity.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

David H. Kruse, Ph.D.
24 July 2006

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.